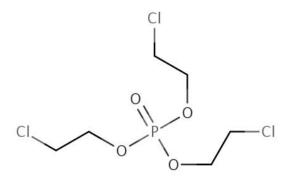


Draft Scope of the Risk Evaluation for Tris(2-chloroethyl) Phosphate

CASRN 115-96-8



April 2020

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Docket

Supporting information can be found in public docket: [Docket ID: EPA-HQ-OPPT-2018-0462].

Disclaimer

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States Government.

ABBREVIATIONS AND ACRONYMS

ADME Absorption, Distribution, Metabolism, and Excretion

BAF Bioaccumulation factor
BCF Bioconcentration factor
BMF Biomagnification factor

CBI Confidential Business Information

CDR Chemical Data Reporting

ChemSTEER Chemical Screening Tool for Exposure and Environmental Releases

CHRIP Chemical Risk Information Platform

COC Concentration of concern

CPCat Chemical and Product Categories
CSCL Chemical Substances Control Law

EC Engineering control

ECHA European Chemical Agency

 EC_x Concentration that causes a response that is x% of the maximum

ESD Emission Scenario Document

FYI For Your Information
GS Generic Scenario

HAP Hazardous Air Pollutant

LC₅₀ Lethal concentration of 50% of the test organisms LC_x Lethal concentration that is x% of the maximum

LOAEL Lowest observed adverse effect level LOEC Lowest observed effect concentration

mm Hg Millimeter(s) of Mercury

NIOSH National Institute for Occupational Safety and Health

NOAEL No observed adverse effect level NOEC No observed effect concentration

ONU Occupational Non-User

OPPT Office of Pollution Prevention and Toxics
OSHA Occupational Safety and Health Administration

PBT Persistent, bioaccumulative, toxic

P-chem Physical-chemical

PECO Population, exposure, comparator, outcome

PEL Permissible Exposure Limit

PESS Potentially Exposed or Susceptible Subpopulation

PNOR Particulates Not Otherwise Regulated
POTW Publicly Owned Treatment Works
PPE Personal Protective Equipment

SDS Safety Data Sheet

TCEP Tris(2-chloroethyl) Phosphate

TIAB Title and abstract

TRI Toxics Release Inventory
WWTP Wastewater Treatment Plant

EXECUTIVE SUMMARY

In December 2019, EPA designated tris(2-chloroethyl) phosphate (TCEP) (CASRN 115-96-8) as a high-priority substance for risk evaluation following the prioritization process required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0476-0007). The first step of the risk evaluation process is the development of the scope document, and this document fulfills the TSCA regulatory requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft scope for TCEP includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. TCEP is a liquid and primarily used as a flame retardant with a total production volume in the United States between 25 and 100 million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for TCEP to inform the development of this draft scope document. To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard), and the search and screening results to date are provided in Section 2.1. EPA is seeking public comment on this draft scope document and will consider additional information identified following publication of this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the Application of Systematic Review in TSCA Risk Evaluations document (U.S. EPA, 2018) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation for TCEP.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of TCEP in the risk evaluation. TCEP is imported into the United States and is primarily used as a flame retardant in paint and coating manufacturing, polyester resin, thermoplastics, and articles, such as aircraft interiors. In addition, TCEP is used as a laboratory chemical. TCEP is incorporated into fabric and textiles as well as paints and coatings. In the past, TCEP was incorporated into foam seating and bedding products, including polyurethane foam, and building and construction materials, such as roofing insulation and wood resin composites. Some of these products may still be present in consumers' homes and commercially. EPA identified these conditions of use from information reported to EPA through Chemical Data Reporting (CDR), published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. In addition, EPA plans to analyze distribution in commerce and disposal as part of the risk evaluation.

Conceptual Model. The conceptual models for TCEP are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways

(e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards, and receptors throughout the life cycle of the chemical substance. EPA plans to focus the risk evaluation for TCEP on the following exposures, hazards, and receptors with the understanding that updates may be made in the final scope document after consideration of public comments and completion of the systematic review data collection phase.

• Exposures (Pathways and Routes), Receptors and PESS. EPA plans to analyze both human and environmental exposures resulting from the conditions of use of TCEP that EPA plans to consider in the risk evaluation. Exposures for TCEP are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of TCEP in surface water, groundwater, biosolids and sediment. Additional information gathered through systematic review searches will also inform expected exposures.

In Section 2.6.3, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of TCEP within the scope of the risk evaluation.

Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- Occupational exposures associated with manufacturing, import, processing and industrial and commercial conditions of use: EPA plans to evaluate exposures to workers and/or occupational non-users via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use, or disposal of TCEP (Section 2.2.2).
- Consumer and bystander exposures associated with consumer conditions of use: EPA
 plans to evaluate the inhalation and dermal exposure to TCEP when consumers are using
 paints and coatings, fabric, textiles and leather products, foam setting and bedding
 products, building/construction materials, wood and engineered wood products
 containing TCEP, and children's mouthing or products/articles containing TCEP.
- General population exposures: EPA plans to evaluate exposure to TCEP via drinking water, groundwater, ambient air, fish ingestion, human breast milk, and soil for the general population.
- Environmental exposures: EPA plans to evaluate exposure to TCEP for aquatic and terrestrial receptors via various pathways including surface water, sediment, and soil.
- Human receptors and PESS: EPA plans to evaluate children, women of reproductive age (including, but not limited to pregnant women), workers, and consumers as receptors and PESS in the risk evaluation.
- Hazards. Hazards for TCEP are discussed in Section 2.4. EPA completed preliminary reviews of
 information from peer-reviewed assessments and databases to identify potential environmental
 and human health hazards for TCEP as part of the prioritization process. Environmental hazard
 effects were identified for aquatic and terrestrial organisms. Information collected through
 systematic review methods and public comments may identify additional environmental hazards
 that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for TCEP. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-response assessment. EPA plans to evaluate all of the potential human health hazards for TCEP identified in Section 2.4.2. The broad health effect categories include reproductive and developmental, nervous system, genotoxicity, carcinogenicity effects.

Analysis Plan. The analysis plan for TCEP is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various information streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of TCEP to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA will continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

EPA will seek public comments on the systematic review methods supporting the risk evaluation for TCEP, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for TCEP will be peer-reviewed. Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations, including using EPA's <u>Peer Review Handbook</u> and other methods consistent with Section 26 of TSCA (See <u>40 CFR</u> 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for tris(2-chloroethyl) phosphate (TCEP) under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

Under TSCA § 6(b), the Environmental Protection Agency (EPA) must designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non- risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high-priority substances for risk evaluations (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. TCEP is one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information ¹ to support the development of this draft scope document for TCEP. EPA leveraged the data and information sources already identified in the documents supporting the chemical substance's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

- 1. Databases containing publicly available, peer-reviewed literature;
- 2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases.
- 3. Data and information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

¹ Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14. (40 CFR 702.33).

After completing the screening of all identified reasonably available information, the Agency will evaluate the quality of relevant information, synthetize and integrate it to form overall conclusions about the potential hazards and exposures to support the risk characterization for TCEP. This systematic review process will be documented and made public as EPA undergoes the risk evaluation process. The details are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document.

The subsequent sections summarize the data collection activities completed up to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for TCEP upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature for All Disciplines

EPA surveyed the gray literature² and identified 101 search results relevant to EPA's risk assessment needs for TCEP. Appendix A lists the gray literature sources that yielded 101 discrete data or information sources relevant to TCEP. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

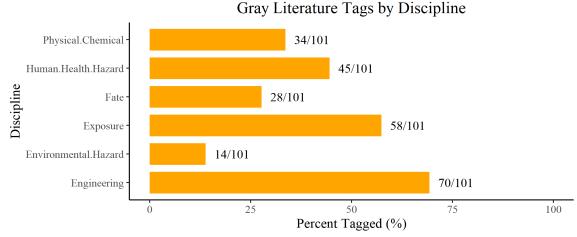


Figure 2-1 Gray Literature Tags by Discipline for TCEP

Note: The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

2.1.1 Search of Literature from Publicly Available Databases (Peer-Reviewed Literature)

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-chemical (p-chem) properties, environmental fate and transport, engineering (environmental release and

² Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (e.g., PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases.

occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of TCEP. Eligibility criteria were applied in the form of population, exposure, comparator, outcome (PECO) or similar statements. Included references met the PECO or similar criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure 2-2 through Figure 2-6. "TIAB" in these figures refers to title and abstract screening. Note that the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

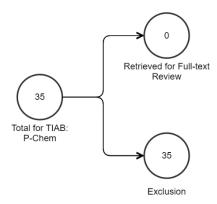


Figure 2-2 Peer-reviewed Literature - Physical-Chemical Properties Search Results for TCEP

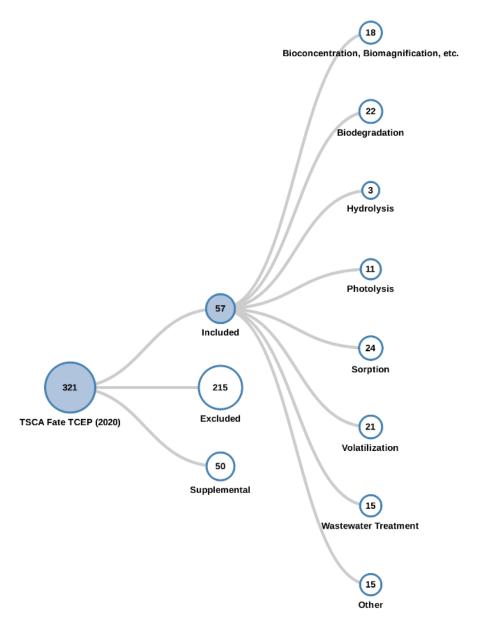


Figure 2-3 Peer-reviewed Literature - Fate and Transport Search Results for TCEP Click here for interactive HAWC (Health Assessment Workspace Collaborative) Diagram.

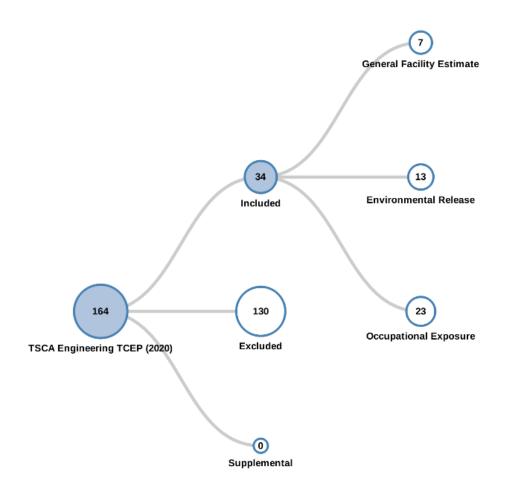


Figure 2-4 Peer-reviewed Literature - Engineering Search Results for TCEP Click <u>here</u> for interactive HAWC Diagram.

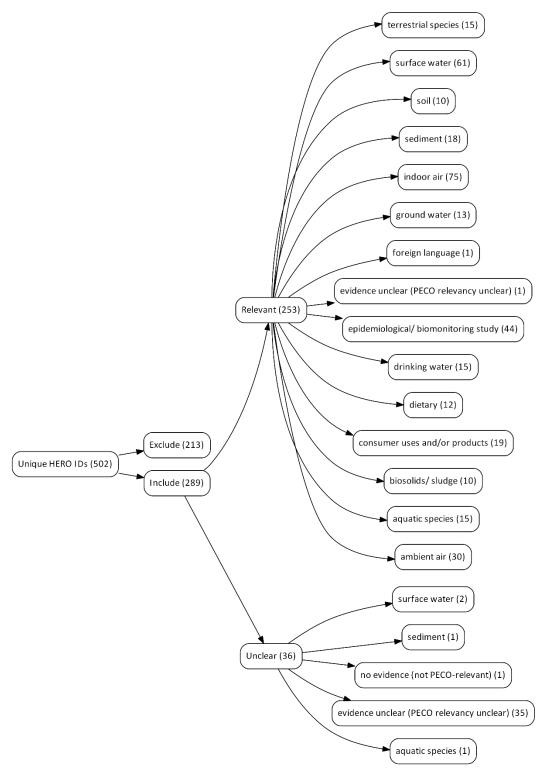


Figure 2-5 Peer-reviewed Literature - Exposure Search Results for TCEP

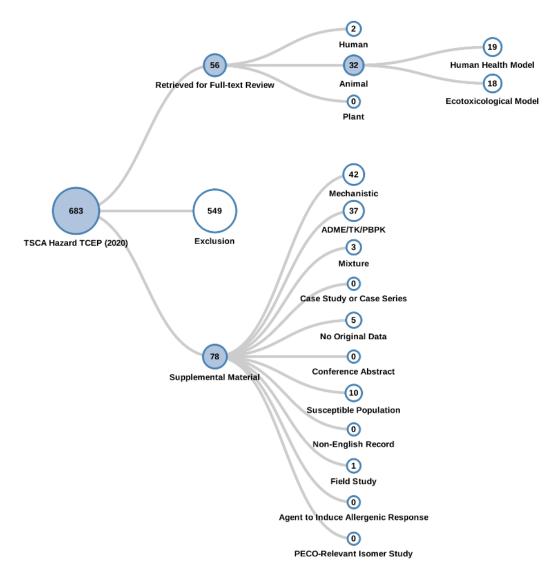


Figure 2-6 Peer-reviewed Literature - Hazard Search Results for TCEP Click <u>here</u> for interactive HAWC Diagram.

2.1.2 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 15 submissions using inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 13 submissions that met the inclusion criteria in these statements and identified 2 submissions with supplemental data. EPA excluded zero submissions. EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full text screening), when more information regarding the reports is available.

Table 2-1 Results of Title Screening of Submissions to EPA under Various Sections of TSCA

| Discipline | Included | Supplemental |
|--|----------|--------------|
| Physicochemical Properties | 1 | 0 |
| Environmental Fate and Transport | 2 | 0 |
| Environmental and General Population Exposure | 4 | 0 |
| Occupational Exposure/Release Information | 1 | 0 |
| Environmental Hazard | 4 | 0 |
| Human Health Hazard | 6 | 2 |

2.2 Conditions of Use

As described in the <u>Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation</u> (U.S. EPA 2019a), EPA assembled information from the CDR program to determine conditions of use³ or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of TCEP, including: published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing TCEP, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, EPA incorporated communications with companies, industry groups, and public comments to supplement the condition of use information.

EPA identified and described the categories and subcategories of conditions of use that EPA plans to include in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use EPA plans to include in the scope are those reflected in the life cycle diagrams and conceptual models.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of TCEP, EPA identified those categories or subcategories of use activities for TCEP the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

2.2.1 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Table lists the conditions of use that are included in the scope of the risk evaluation. Appendix E provides additional descriptions of the uses.

³ Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

Table 2-2 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

| Evaluation | | | |
|--------------------------|--|---|--|
| Life Cycle Stage | Category | Subcategory | References |
| Manufacturing | Import | Import | U.S. EPA (2019b) |
| Processing | Processing – incorporation into formulation, mixture or reaction product | Flame retardant in: Paint and coating manufacturing | U.S. EPA (2019b); Duratec Surfacing Technology (2018); BJB Enterprises (2018) |
| | Processing – incorporation into formulation, mixture or reaction product | Flame retardant in: Polyester resin | EPA-HQ-OPPT-2018-0476- 0015 |
| | Processing – incorporation into formulation, mixture or reaction product | Flame retardant in: Thermoplastics | EPA-HQ-OPPT-2018-0476- 0012 |
| | Processing – incorporation into article | Flame retardant (e.g., aircraft interiors) | EPA-HQ-OPPT-2018-0476- 0006 |
| | Recycling | Recycling | U.S. EPA (2019b) |
| Distribution in commerce | Distribution in commerce | Distribution in commerce | |
| Industrial Use | Other use | Aircraft interiors and aerospace products | EPA-HQ-OPPT-2018-0476- 0006 |
| Commercial Use | Other use | Aircraft interiors and aerospace products | EPA-HQ-OPPT-2018-0476- 0006 |
| Commercial Use | Paints and coatings | Paints and coatings | U.S. EPA (2019b) |
| Osc | Other use | e.g., Laboratory chemicals | TCI America (2018) |
| | Furnishing, Cleaning, Treatment/Care Products | Fabric, textile, and leather products not covered elsewhere | EPA-HQ-OPPT-2018-0476- 0015 |
| | Construction, Paint, Electrical, and Metal Products | Building/construction materials not covered elsewhere (e.g., roofing insulation) | EPA-HQ-OPPT-2018-0476- 0015; Environment Canada (2009) cites Plastics Technology (2009) |
| | Furnishing, Cleaning, Treatment/Care Products | Foam Seating and Bedding Products | Stapleton (2011) |

| Life Cycle Stage | Category | Subcategory | References |
|---------------------|---|---|--|
| ŭ . | Construction, Paint, Electrical, and Metal Products | Building/construction materials - wood and engineered wood products (e.g., composites) | Environment Canada (2009) cites IARC (1990); IPCS (1998); EC (2009); OECD (2006) |
| Consumer Use | Paints and coatings | Paints and coatings | U.S. EPA (2019b) |
| | Furnishing, Cleaning, Treatment/Care Products | Fabric, textile, and leather products not covered elsewhere | EPA-HQ-OPPT-2018-0476- 0015 |
| | Construction, Paint, Electrical, and Metal Products | Building/construction materials not covered elsewhere (e.g., roofing insulation) | EPA-HQ-OPPT-2018-0476- 0015; Environment Canada (2009) cites Plastics Technology (2009) |
| | Furnishing, Cleaning, Treatment/Care Products | Foam Seating and Bedding Products | Stapleton (2011) |
| | Construction, Paint, Electrical, and Metal Products | Building/construction materials - wood and engineered wood products (e.g., wood resin composites) | Environment Canada (2009) cites IARC (1990); IPCS (1998); EC (2009); OECD (2006) |
| Disposal | Disposal | Disposal | |

- Life Cycle Stage Use Definitions (40 CFR § 711.3)
- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA the authority to determine what constitutes a condition of use for a particular chemical substance. EPA does not plan to include in this scope or in the risk evaluation activities that the Agency has concluded do not constitute conditions of use. No conditions of use were excluded for TCEP.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of TCEP in 2015 was 25,000 to 100,000 pounds (U.S. EPA, 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that are considered within the scope of the risk evaluation for the various life cycle stages as presented in Section 2.2.1. Section 2.2.3 summarizes the descriptions of the industrial, commercial and consumer use categories and included in the life cycle diagram. The activities that EPA determined are out of scope are not included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses).⁴

⁴ The descriptions are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting.

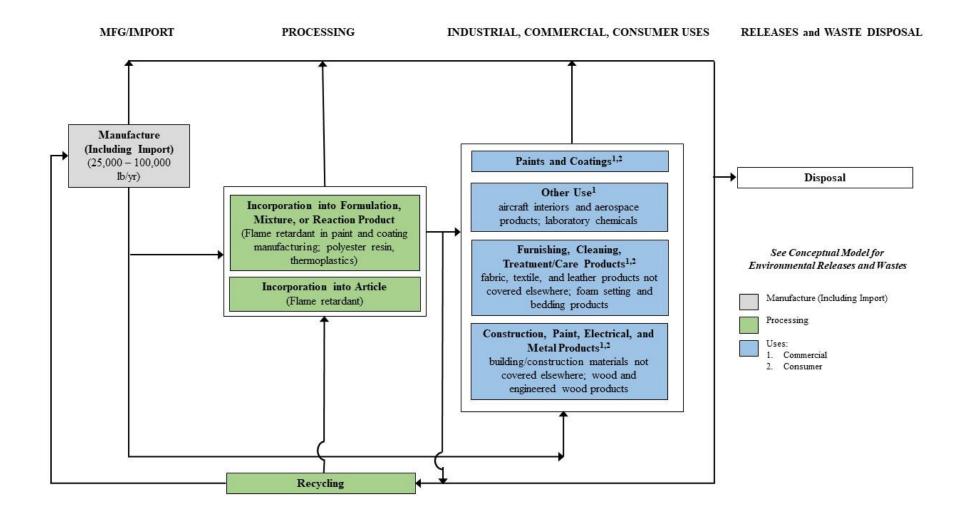


Figure 2-7 TCEP Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and industrial, commercial, and consumer uses as specific production volume is claimed confidential business information (CBI), withheld pursuant to TSCA section § 14 or unknown. There may be additional activities and uses not shown in the diagram that are claimed CBI.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for TCEP. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and environmental receptors. EPA plans to take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to TCEP.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019) to support the development of the risk evaluation for TCEP. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for TCEP. EPA plans to use the environmental fate characteristics described in the <u>Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation</u> to support the development of the risk evaluation for TCEP. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use are a component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

TCEP is not reported to the Toxics Release Inventory (TRI). There may be releases of TCEP from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill. Articles that contain TCEP may release TCEP to the environment during use or through recycling and disposal. EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for TCEP.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of TCEP can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota) via surface water, sediment, soil and ambient air. Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, bioaccumulation and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review available environmental exposure data in biota in the risk evaluation. Monitoring data were identified in EPA's search for reasonably available information on environmental exposures in biota to inform development of the environmental exposure assessment for TCEP. Relevant and reliable monitoring

studies provide information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

EPA plans to review available environmental monitoring data for TCEP. USGS's Monitoring Data - National Water Quality Monitoring Council has identified TCEP in surface water, ground water and sediment. In the screening study from the Norwegian Arctic (Evenset, 2009), TCEP were detected in the fish samples (< 0.6 - 26 ng/g ww) and TCEP was detected in the seabird samples (< 0.5 - 4.7 ng/g ww). TCEP in herring gull eggs from the Lake Huron area in the US have been measured (Chen et al., 2012).

In Sengupta et al., 2014, water samples were collected during two low-flow events at locations above and below the discharge points of water reclamation plants in Southern California. TCEP was quantified found in aggregate with other chemicals chlorinated chemicals.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA plans analyze exposure to occupational non-users (ONUs), workers who do not directly handle the chemical but perform work in an area where the chemical is present. EPA also plans to consider the effect(s) that engineering controls (ECs) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

EPA plans to evaluate potential exposures from the processing of the chemical as it is incorporated into formulations and products. TCEP is used as an additive flame retardant. In general, EPA plans to evaluate the potential for exposure from additive flame retardants due to blooming and release from article components during their manufacture and industrial/commercial use.

Worker activities associated with the conditions of use within the scope of the risk evaluation for TCEP that will be analyzed, include, but are not limited to:

- Unloading and transferring TCEP to and from storage containers to process vessels during manufacturing, processing and use;
- Handling, transporting and disposing of waste containing TCEP during manufacturing, processing, use and recycling;
- Cleaning and maintaining equipment during manufacturing, processing, uses and recycling;
- Sampling chemicals, formulations or products containing TCEP for quality control during manufacturing, processing, use and recycling;
- Performing other work activities in or near areas where TCEP is used.
- Repackaging chemicals, formulations or products containing TCEP during manufacturing, processing, use and recycling.

TCEP can exist as a liquid and a wet solid and reported vapor pressure varies widely: 8.6×10^{-6} mm Hg at 20 °C and ranging between 1.6×10^{-5} mm Hg at 25 °C. EPA anticipates inhalation of mist, dust and/or other respirable particles as an exposure pathway for workers and occupational non-users during the manufacture, processing, and commercial/industrial use of various products containing TCEP (for example, particulate generated during manufacture and handling of foam and incorporation of foam other article components into finished products, and mist generated during application to textiles and application of paints and coatings). Occupational exposure limits for TCEP have not been established by the Occupational Safety and Health Administration (OSHA), the American Conference of Government

Industrial Hygienists (ACGIH), or the National Institute for Occupational Safety and Health (NIOSH). However, the OSHA Permissible Exposure Limit (PEL) for Particulates Not Otherwise Regulated (PNOR) (15 mg/m³) may be applicable if particulate matter containing TCEP is generated during industrial operations.

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths, ingest inhaled particles that deposit in the upper respiratory tract or consume contaminated food. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider oral exposure on a case-by-case basis for certain COUs and worker activities where there is information and data on incidental ingestion of inhaled dust. EPA will consider ingestion of inhaled dust as an inhalation exposure for TCEP.

EPA anticipates dermal exposure to workers from contact with liquids during packaging and repackaging operations at import sites when TCEP is handled as a liquid. EPA also anticipates dermal exposure to solids during these operations if TCEP is formulated with solid chemicals and handled as a solid.

2.3.6 Consumer Exposures

TCEP appears to be widely used in consumer products, specifically paints and coatings, electrical and electronic products, building/construction materials, and batteries. The main exposure routes for these uses where consumers interact with products and articles containing TCEP are dermal, inhalation, and dust ingestion, including children's mouthing of articles (e.g., plastics, textiles, wood products) containing TCEP.

2.3.7 General Population Exposures

Releases of TCEP from certain conditions of use, such as manufacturing, processing or disposal activities, may result in general population exposures. EPA plans to evaluate the reasonably available literature for the presence of TCEP in drinking water, ground water, ambient air, indoor air, fish, human breast milk, and dust and soil, which may be mouthed or ingested.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for TCEP. EPA considers all the potential environmental hazards for TCEP identified during prioritization (U.S. EPA 2019) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with TCEP. If necessary, EPA plans to update the list of potential hazards in the final scope document of TCEP. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation (U.S. EPA, 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for TCEP. EPA plans to consider all the potential human health hazards for TCEP identified during prioritization (U.S. EPA, 2019). The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and absorption, distribution, metabolism, and excretion (ADME). The broad health effect categories include reproductive and developmental, nervous system, hepatic, renal and other effects after single or repeated exposure to TCEP. Epidemiological or biomonitoring studies were identified reporting health effects after exposure to TCEP. Studies were identified reporting information on genotoxicity, carcinogenicity, and ADME. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the TCEP risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population for adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

During the Prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (including, but not limited to pregnant women), workers, and consumers (U.S. EPA, 2019). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

In developing exposure scenarios, EPA plans to analyze reasonably available information to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors, ingestion of breast milk) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of TCEP. Pathways and routes of exposure associated with workers and occupational non-users are described in Section 2.6.1, and

pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes are discussed and depicted the conceptual model shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of TCEP that EPA plans to include in the risk evaluation. There is potential for exposure to workers and/or occupational non-users via inhalation routes and exposures to workers via dermal routes. Dermal exposure to TCEP in both liquid and solid form is expected, as TCEP can be used/transported in liquid or wet solid form. Additionally, potential inhalation exposures to TCEP in mist or dust form are expected for certain conditions of use. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not each combination of exposure pathway, route, and receptor will be assessed in the risk evaluation. The supporting rationale are presented in Appendix F.

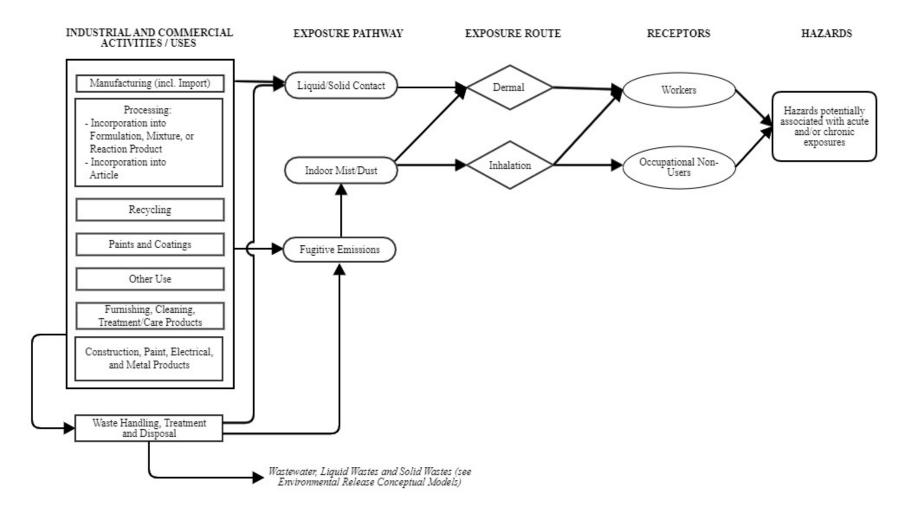


Figure 2-8 Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses TCEP.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TCEP that EPA plans to include in the risk evaluation. EPA expects inhalation and dermal to be the primary routes of exposure and plans to evaluate inhalation exposures to TCEP vapors or dust containing TCEP for consumers and bystanders. There is potential for dermal exposures to TCEP via direct contact with liquid or solid products or articles containing TCEP during consumer uses, and inhalation exposures to TCEP via dust, vapor or mist generated from use of consumer products. There is also potential for oral ingestion of dust containing TCEP – for example, via children's hand-to-mouth behavior. The supporting rationale for consumer pathways that are in scope for TCEP are included in 2.8Appendix G.

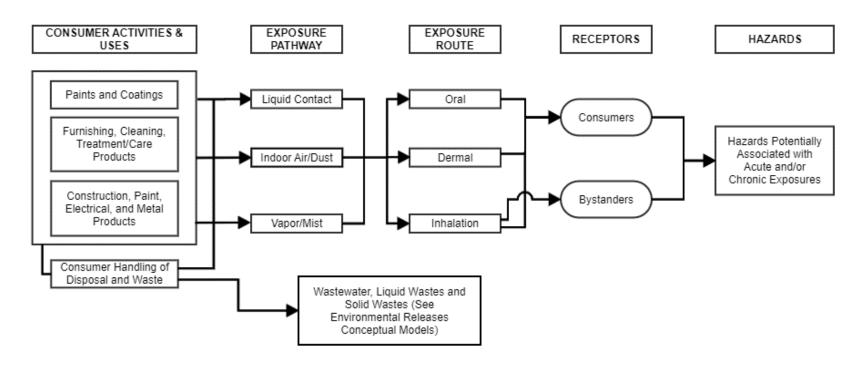
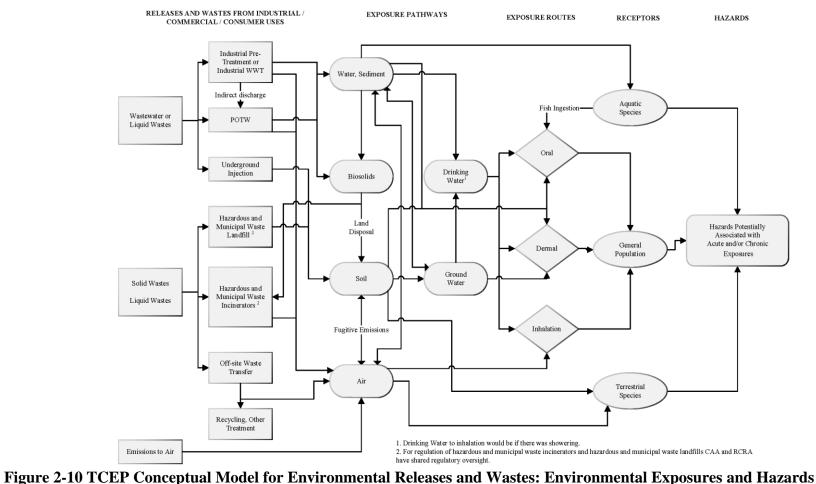


Figure 2-9 TCEP Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

2.6.3 Conceptual Model for Environmental Releases and Wastes

Figure 2-10 presents the exposure pathways, exposure routes, and hazards to human and environmental receptors for releases and waste streams associated with environmental releases of TCEP. EPA plans to evaluate pathways and routes of exposures to receptors (e.g., general population, aquatic, terrestrial species) that may occur from industrial and/or commercial uses, releases to air, water or land, including biosolids and soil, and other conditions of use. EPA expects humans to be exposed to TCEP from air emissions via inhalation as well as from water, liquid, and solid waste releases - orally via drinking water, fish and soil ingestion, and dermally from contact with groundwater and soil. The supporting rationale for general population and environmental pathways considered for TCEP are included in Appendix H.



Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to a POTW. Drinking water will undergo further treatment in

drinking water treatment plant. Ground water may also be a source of drinking water. Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of TCEP to date which includes a partial, but not complete review of reasonably available information as described in Section 2.1. EPA encourages submission of additional data, such as full study reports or workplace monitoring from industry sources, that may be relevant for EPA's evaluation of conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. Further, EPA may consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure. EPA will continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document. As discussed in the Application of Systematic Review in TSCA Risk Evaluations document [EPA Document #740-P1-8001], targeted supplemental searches during the analysis phase may be necessary to identify additional reasonably available information (e.g., commercial mixtures) for the risk evaluation of TCEP.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical (p-chem) properties and environmental fate and transport of TCEP as follows:

- 1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
 - EPA plans to review data and information collected through the systematic review methods and public comments about the p-chem properties (Appendix B) and fate endpoints (Appendix C) previously summarized in the *Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a). All sources cited in EPA's analysis will be reviewed according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.
- 2) Using measured data and/or modeling, determine the influence of p-chem properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.

 Measured data and, where necessary, model predictions of p-chem properties and environmental fate endpoints will be used to characterize the persistence and movement of TCEP within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) Conduct a weight-of-evidence evaluation of p-chem and environmental fate data, including qualitative and quantitative sources of information.

During risk evaluation, EPA plans to evaluate and integrate the p-chem and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels to TCEP via indoor air, ambient air, surface water, sediment, soil, aquatic biota and terrestrial biota. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios are combinations of sources (uses), exposure pathways and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for TCEP are presented in Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures.

Based on their p-chem properties, expected sources and transport and transformation within the outdoor and indoor environment, chemical substances are more likely to be present in some media and less likely to be present in others. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.

EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix A. EPA plans to continue to review data sources identified in Appendix A during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are:

Table 2-3 Categories and Sources of Environmental Release Data

| Table 2-3 Categories and Sources of Environmental Release Data |
|--|
| U.S. EPA Generic Scenarios |
| OECD Emission Scenario Documents |
| EU Risk Assessment Report |
| Discharge Monitoring Report (DMR) surface water discharge data for TCEP from |
| NPDES-permitted facilities. |

EPA plans to consider using the manufacture and import volume identified in CDR to estimate releases resulting from repackaging of imported TCEP and subsequent processing.

Furthermore, EPA plans to consider whether scrap articles and used finished products containing TCEP are recycled. If EPA proceeds with the evaluation of any of the recycling processes, then EPA may perform targeted data searches as needed.

2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies). EPA plans to continue to review relevant data sources as identified in Appendix B during the risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use.

Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases (ChemSTEER) (EPA, 2016).

3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.

EPA has not yet identified surrogate chemicals and data that can be used to estimate releases from uses of TCEP. EPA plans to review release data for surrogate chemicals that have uses and chemical and physical properties similar to TCEP as it is identified. EPA may conduct targeted searches for surrogate data.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.

This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding release scenarios).

5) Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.

EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Plastics Additives and the 2011 ESD on the Chemical Industry may be useful. EPA plans to need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

Generic Scenarios that contain information that may be related to the potential uses of TCEP include, but are not limited to:

- EPA's Additives in Plastics Processing (Compounding) Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases (May 2004);
- EPA's Spray Coatings in the Furniture Industry Generic Scenario for Estimating Occupational Exposures and Environmental Releases (April 2004);
- EPA's Leather Dyeing Generic Scenario for Estimating Occupational Exposures and Environmental Releases (September 2000);
- EPA's Fabric Finishing Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases (September 1994);

- EPA's Application of Spray Polyurethane Foam Insulation Generic Scenario for Estimating Occupational Exposures and Environmental Releases (March 2019);
- EPA's Industry Profile for the Flexible Polyurethane Foam Industry- Generic Scenario for Estimating Occupational Exposures and Environmental Releases (February 2004); and,
- EPA's Industry Profile for the Rigid Polyurethane Foam Industry Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases (September 2004).

OECD Emission Scenario Documents are available at the following: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

ESDs that contain information that may be related to the potential uses of TCEP include, but are not limited to:

- OECD's Complementing Document to the ESD On Plastic Additives: Plastic Additives During the Use of End Products (May 2019);
- OECD's Complementing Document for ESD on Coating Industry: Application of Paint Solvents for Industrial Coating (December 2015);
- OECD's ESD on the Chemical Industry (September 2011);
- OECD's ESD on Radiation Curable Coating, Inks, and Adhesives (July 2011);
- OECD's ESD on Plastic Additives (July 2009); and
- OECD's ESD on Coating Industry (Paints, Lacquers and Varnishes) (July 2009).

6) Map or group each condition of use to a release assessment scenario(s).

EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix H. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g., recycling, construction and demolition). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping/grouping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) Evaluate the weight of the scientific evidence of environmental release data.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of TCEP:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.

For TCEP, environmental media which plans to evaluate are sediment, biosolids, soil, air, and water. The environmental exposure pathways which have been identified in the literature include aquatic and terrestrial.

- 2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. EPA plans to analyze reasonably available environmental exposure models that meet the TSCA Section 26(h) and (i) Science Standards and that estimate surface water, sediment, and soil concentrations alongside reasonably available surface water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations, and soil concentrations generally consider the following inputs: direct release into surface water, sediment, or soil (i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).
- 3) Review reasonably available environmental monitoring data for vegetation, invertebrates, fish, non-fish vertebrates (i.e., amphibians, reptiles, mammals). Plan to consider whether these data could be used to compare with comparable species or taxa-specific toxicological benchmarks.

EPA plans to analyze predatory bird species that consume fish with elevated levels of TCEP. If species-specific environmental monitoring data matches toxicity studies, direct comparisons can be made. EPA plans to consider refining data for other species by using body weight of the birds, fish ingestion rate of birds, and typical fish species consumed.

4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.

There have been changes to use patterns of TCEP over the last few years. Monitoring data or modeled estimates will be reviewed to determine how representative they are of applicable use patterns.

EPA plans to evaluate any studies which relate levels of TCEP in the environment or biota with specific sources or groups of sources.

5) Group each condition(s) of use to environmental assessment scenario(s).

EPA plans to refine and finalize exposure scenarios for environmental receptors by considering combinations of sources, exposure pathways including routes and populations exposed. For TCEP, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

- Estimates of surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on available monitoring data.
- Modeling inputs such as releases into the media of interest, fate and transport and characteristics of the environment.
- Reasonably available biomonitoring data, which could be used to compare with species or taxa-specific toxicological benchmarks.

- Applicability of existing additional contextual information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

6) Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using systematic review methods.

2.7.2.3 Occupational Exposures

EPA plans to analyze both worker and occupational non-user exposures as follows:

- 1) Review reasonably available exposure monitoring data for specific condition(s) of use. EPA plans to review available TCEP exposure monitoring data for specific conditions of use. Example exposure data include workplace monitoring data collected by government agencies such as OSHA and NIOSH, and monitoring data in published literature. The data may include both personal exposure monitoring measurements and area monitoring measurements.
- 2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to TCEP.
 EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.
- 3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.

For conditions of use where data are not available, EPA plans to review existing exposure models that may be applicable in estimating exposure levels of TCEP.

EPA has identified potentially relevant OECD ESDs and EPA Generic Scenarios corresponding to some conditions of use. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA may conduct industry outreach efforts or perform supplemental, targeted literature searches to better understand the process steps involved in conditions of use. EPA plans to also consider the applicability of exposure models in the Chemical Screening Tool for Occupational Exposure and Releases (ChemSTEER) (U.S. EPA, 2016) tool that are routinely used for assessing new chemicals to assess exposures during various conditions of use. EPA may also perform targeted research to identify other models that EPA could use to estimate exposures for certain conditions of use.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.

This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models

developed by EPA or other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to occupational non-users.

5) Consider and incorporate applicable engineering controls (ECs) and/or personal protective equipment (PPE) into exposure scenarios.

EPA plans to review potentially relevant data sources on ECs and PPE as identified in Appendix E to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of ECs, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) Map or group each condition of use to occupational exposure assessment scenario(s). EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use. As presented in Appendix F, EPA has grouped the scenarios into representative release/exposure scenarios, all of which will be evaluated. EPA was not able to identify occupational scenarios corresponding to some conditions of use (e.g., recycling, construction and demolition). EPA may further refine the mapping/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

EPA plans to analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) Group each condition of use to consumer exposure assessment scenario(s).

Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes and exposed populations.

For TCEP, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use and type of consumer product
- Duration, frequency and magnitude of exposure

- Weight fraction of chemical in products
- Amount of chemical used

2) Evaluate the relative potential of indoor exposure pathways based on reasonably available data.

Indoor exposure pathways expected to be relatively higher include particle inhalation, dust ingestion, and dermal contact as a result of indoor use of TCEP consumer products. Indoor exposure pathways expected to be relatively lower include inhalation of vapor and mist and liquid and mist oral ingestion. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) Review existing indoor exposure models that may be applicable in estimating indoor air, indoor dust concentrations, or indoor dust surface loadings.

Indoor exposure models that estimate emission and migration of SVOCs into the indoor environment are available. These models generally consider mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient, and the material-air partition coefficient. In addition, direct transfer to surface dust or physical abrasion may influence emissions over time. These properties vary based on p-chem properties and properties of the material. The OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

4) Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.

To the extent other organizations have already modeled a TCEP consumer exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to TCEP have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting TCEP in specific media (e.g., dust or indoor air).

The availability of TCEP concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air and dust levels and various indoor sources will be analyzed.

6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

7) Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.

EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) Refine and finalize exposure scenarios for general population by considering sources and uses, exposure pathways including routes, and exposed populations.

For TCEP, the following are noteworthy considerations in constructing exposure scenarios for the general population: routes of exposure, releases to air, water or land resulting from industrial, commercial, and other conditions of use, in addition to:

- Review of reasonably available environmental and biological monitoring data for media to which general population exposures are expected;
- For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels;
- Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling;
- Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available;
- Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data;
- Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined:
- Evaluate the weight of the scientific evidence of general population exposure data; and
- Mapping or grouping each condition of use to general population exposure assessment scenario(s).

EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix G. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or

quantitative, and is dependent upon reasonably available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with reasonably available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups. If available, EPA plans to compare multiple scenario-specific and background exposure doses estimated from media-specific concentrations and exposure factors with available biomonitoring data. The forward-calculated and backcalculated exposures could be compared to characterize the relative contribution from defined exposure scenarios.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is reasonably available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and will require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

- 2) Review reasonably available environmental and biological monitoring data for exposure pathways and media to which general population exposures are expected.

 General population exposure pathways expected to be relatively higher include: ingestion of water and food including fish, root crops, and mother's milk. General population exposure pathways expected to be relatively lower include: dermal contact to TCEP via liquids, and inhalation of TCEP via vapors, mists and dusts. The data sources associated with these respective pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.
- 3) For exposure pathways where empirical data is not available, review existing exposure models that may be applicable in estimating exposure levels.
 For TCEP, media where exposure models will be considered for general population exposure include models that estimate, surface water concentrations, sediment concentrations, soil concentrations and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.
- 4) Review reasonably available exposure modeled estimates. For example, existing models developed for a previous TCEP chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are available.

To the extent other organizations have already modeled TCEP general population exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.

For TCEP, exposure scenarios that involve potentially exposed or susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for soil than adults.

6) Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).

For TCEP, exposure scenarios that involve potentially exposed or susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for dust, soil, and diet than adults.

7) Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of TCEP as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).

EPA plans to analyze the hazards of TCEP to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g., analogue and read-across data) when characterizing the potential hazards of TCEP to aquatic and/or terrestrial organisms.

Environmental hazard data will be evaluated using the environmental toxicity data quality criteria outlined in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

Hazard endpoints (e.g., mortality, growth, immobility, reproduction) will be evaluated, while considering data availability, relevance, and quality.

2) Derive hazard thresholds for aquatic and/or terrestrial organisms.

Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x. LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of TCEP to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

- 3) Evaluate the weight of the scientific evidence of environmental hazard data.
 - During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.
- 4) Consider the route(s) of exposure, based on available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments.

 EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the TCEP conceptual model. These organisms may be exposed to TCEP via a number of environmental pathways (e.g., surface water, sediment, soil, diet).
- 5) Conduct an environmental risk characterization of TCEP.

EPA plans to conduct a risk characterization of TCEP to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of TCEP in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of TCEP. EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of TCEP after reviewing relevant p-chem properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of TCEP. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC₅₀, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for TCEP with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies; systems biology). Human health studies will be evaluated using the evaluation strategies laid out in the Applications of Systematic Review under TSCA document.

Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.

Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to TCEP hazard(s). Susceptibility of particular human receptor groups to TCEP will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with potentially exposed or susceptible populations and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for TCEP exposure. Children, women of reproductive age, workers and consumers are subpopulations who may be potentially exposed or susceptible subpopulations. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.

EPA plans to identify and evaluate human health hazards from acute and chronic exposures by analyzing the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

Dose-response assessment will be performed in accordance with EPA guidance (<u>U.S. EPA</u>, <u>2012a</u>, <u>2011</u>, <u>1994</u>). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not available or would not alter the analysis.

The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to TCEP, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.

Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

- 5) Evaluate the weight of the scientific evidence of human health hazard data.

 During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.
- 6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment. At this stage of review, EPA believes there will be sufficient reasonably available data to conduct dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to TCEP, which could be important for worker, consumer, and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes. This may include using route-to-route extrapolation methods where appropriate and depending on the nature of available data.

If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in EPA's guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's <u>Risk Characterization Policy</u>, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA plans to further carry out the requirements under TSCA Section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the

reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

EPA plans to also be guided by EPA's Information Quality Guidelines (U.S. EPA 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, EPA plans to identify in the risk characterization the following: (1) Each population addressed by an estimate of applicable risk effects; (2) The expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) Each appropriate upper-bound or lower-bound estimate of risk; (4) Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) Peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40">40">40">40">40">60">67R 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for TCEP will be peer reviewed.

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Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1 Gray Literature Sources that Yielded Results for TCEP

| Source/ Agency | Source Name | Source Type | Source Category |
|---|---|---------------------------------|-----------------------------------|
| ATSDR | ATSDR Tox Profile Updates and Addendums | Other US Agency Resources | Assessment or Related Document |
| Australian Government Department of Health | NICNAS Assessments (human health, Tier I, II or III) | International Resources | Assessment or Related Document |
| CPSC | Technical Reports: Exposure/Risk Assessment | Other US Agency Resources | Assessment or Related Document |
| CPSC | Technical Reports: Toxicity Review | Other US Agency Resources | Assessment or Related Document |
| ЕСНА | European Union Risk Assessment Report | International Resources | Assessment or Related Document |
| ЕСНА | Annex XV Restriction Report | International Resources | Assessment or Related Document |
| ЕСНА | Annex XIV Restriction Report | International Resources | Assessment or Related Document |
| Env Canada | Screening Assessment for the Challenge | International Resources | Assessment or Related Document |
| Env Canada | nv Canada Chemicals at a Glance (fact sheets) | | Assessment or Related Document |
| Env Canada | Canada Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment | | Assessment or Related Document |
| EPA | Office of Water: STORET and WQX | US EPA Resources | Database |

| Source/ Agency | Source Name | Source Type | Source Category |
|-------------------|--|----------------------------|--------------------------------|
| EPA | Design for the Environment (DfE) Alternatives Assessments | US EPA Resources | Assessment or Related Document |
| EPA | Included in 2011 NATA | US EPA Resources | Assessment or Related Document |
| EPA | PPRTV Derivation Support Document | US EPA Resources | Assessment or Related Document |
| EPA | Other EPA: Misc sources | US EPA Resources | General Search |
| EPA | EPA: AP-42 | US EPA Resources | Regulatory Document or List |
| EPA | Chemical Data Reporting (2012 and 2016 non-CBI CDR database) | US EPA Resources | Database |
| EPA | Chemical Data Reporting (2012 and 2016 CBI CDR database) | US EPA Resources | Database |
| EPA | EPA: Generic Scenario | US EPA Resources | Assessment or Related Document |
| EPA | EPA Discharge Monitoring Report Data | US EPA Resources | Database |
| EPA | Office of Water: CFRs | US EPA Resources | Regulatory Document or List |
| EPA | Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008) | | Database |
| EPA | Office of Air: CFRs and Dockets | US EPA Resources | Regulatory Document or List |
| IARC | IARC Monograph | International Resources | Assessment or Related Document |
| Japan | Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table) | International Resources | Regulatory Document or List |

| Source/ Agency | Source Name | Source Type | Source Category |
|-------------------|---|---------------------------------|-----------------------------------|
| KOECT | Kirk-Othmer Encyclopedia of Chemical Technology Journal Article | Other Resource | Encyclopedia |
| NIOSH | CDC NIOSH - Health Hazard Evaluations (HHEs) | Other US Agency Resources | Assessment or Related Document |
| NIOSH | CDC NIOSH - Workplace Survey Reports | Other US Agency Resources | Assessment or Related Document |
| NLM | National Library of Medicine's Hazardous Substance Databank | Other US Agency Resources | Database |
| NLM | National Library of Medicine's HazMap | Other US Agency Resources | Database |
| NTP | Technical Reports | Other US Agency Resources | Assessment or Related Document |
| OECD | OECD Substitution and Alternatives Assessment | International Resources | Assessment or Related Document |
| OECD | OECD Emission Scenario Documents | International Resources | Assessment or Related Document |
| OECD | OECD: General Site | International Resources | General Search |
| OSHA | U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG] | Other US Agency Resources | Database |
| RIVM | RIVM Reports: Risk Assessments | International Resources | Assessment or Related Document |
| TERA | Toxicology Excellence for Risk Assessment | Other Resources | Assessment or Related Document |

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

This appendix provides p-chem information and data found in preliminary data gathering for TCEP. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0476).

Table_Apx B-1 Physical and Chemical Properties of TCEP

| Property or Endpoint | Value ^a | Reference | Data Quality Rating |
|---|---|----------------|------------------------|
| Molecular formula | C ₆ H ₁₂ Cl ₃ O ₄ P | NA | NA |
| Molecular weight | 285.49 g/mol | NA | NA |
| Physical state | Liquid | NLM, 2015 | High |
| Physical properties | Clear, transparent liquid | NLM, 2015 | High |
| Melting point | -55°C | NLM, 2015 | High |
| Boiling point | 330°C | NLM, 2015 | High |
| Density | 1.39 g/cm ³ at 25°C | Haynes, 2014 | High |
| Vapor pressure | 0.0613 mm Hg at 25°C | NLM, 2015 | High |
| Vapor density | Not available | | |
| Water solubility | 7820 mg/L at 20°C | NLM, 2015 | High |
| Log Octanol/water partition coefficient (Log Kow) | 1.78 | NLM, 2015 | High |
| Henry's Law constant | 2.55×10 ⁻⁸ atm·m³/mole at 25°C (Bond method) | U.S. EPA, 2012 | |
| Flash point | 222°C | RSC, 2019 | Medium |

| Property or Endpoint | Value ^a | Reference | Data Quality Rating |
|----------------------|--------------------|--------------|------------------------|
| Auto flammability | Not available | | |
| Viscosity | 45 cP at 20°C | NLM, 2015 | High |
| Refractive index | 1.4721 | Haynes, 2014 | High |
| Dielectric constant | Not available | | |

^a Measured unless otherwise noted.

NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1 Environmental Fate Characteristics of TCEP

| Property or Endpoint | Value ^a | References |
|-------------------------------|--|---|
| Direct Photodegradation | Not expected to be susceptible to direct photolysis by sunlight because the chemical structure of TCEP does not contain chromophores that absorb at wavelengths >290 nm | HSDB (2015) |
| Indirect Photodegradation | $t_{1/2} = 5.8$ hours (based on ·OH rate constant of $2.2 \times 10\text{-}11 \text{ cm}^3\text{/molecule-sec}$ at 25 °C and 12-hour day with $1.5 \times 10^6 \cdot \text{OH/cm}^3$; estimated) ^b | U.S. EPA (2012a) |
| Hydrolysis | $t_{1/2}$ = stable at pH 3 $t_{1/2}$ = 3,980 days at pH 7 $t_{1/2}$ = 101 days at pH 10 | EnvCanada (2009) citing Brown et al. (1975) |
| Biodegradation (Aerobic) | Water: 4%/28 days based on BOD 0%/28 days based on TOC 1%/28 days based on HPLC Test substance concentration 100 ppm (MITI test) | NITE (2010); ECHA (2019) |
| | Water: 10%/27 days (OECD 302B) 15%/21 days (OECD 302B) in activated non- adapted industrial sludge | EnvCanada (2009); EC (2000) |
| | 4 and 13%/28 days (OECD 301B) at 20 and 10 mg/L test substance concentration in activated domestic sludge, adaption not specified | |
| | 70–90%/48 days (OECD 301B) at 20 mg/L test substance concentration in activated domestic sludge, adaption not specified | |
| | Soil: DT50 = 167 days, DT90 >>100 days based on test substance concentration 5 mg/kg in standard soil laboratory test | EnvCanada (2009) |
| Biodegradation (Anaerobic) | Soil: 0%/58 days at 80 mg/L test substance concentration related to DOC (ISO DIS 11734) | EC (2000) citing Noack (1993) |
| Wastewater Treatment | 9.2% total removal (7.3% by biodegradation, 1.9 by sludge and 0% by volatilization to air; estimated) ^b | U.S. EPA (2012a) |
| Bioconcentration Factor | 0.6–0.8 and ≤1.2–5.1 at test substance concentrations of 0.1 and 1.0 ppm (w/v), respectively (<i>Cyprinus carpio</i>) | NITE (2010) |

| Property or Endpoint | Value ^a | References |
|---|--|------------------|
| Bioaccumulation Factor | 6.3 (estimated) ^b | U.S. EPA (2012a) |
| Soil Organic Carbon:Water Partition Coefficient (Log Koc) | 2.6 (Koc = 388; MCI method); 2 (Koc = 103; KOW method) (estimated) ^b | U.S. EPA (2012a) |

Notes:

Abbreviations and acronyms: TOC = total organic carbon; HPLC = High-Performance Liquid Chromatography; DOC = dissolved organic carbon;—OH = hydroxyl radical; OECD = Organization for Economic Cooperation and Development; TG = test guideline; GC = gas chromatography; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand

^a Measured unless otherwise noted;

 $[^]b$ EPI SuiteTM physical property inputs: Log KOW = 1.78, BP = 330 °C, MP = -55 °C, VP = 1.6 × 10-5 mm Hg, WS = 7,820 mg/L, SMILES O=P(OCCCl)(OCCCl)OCCCl

Appendix D REGULATORY HISTORY

D.1 Federal Laws and Regulations

Table_Apx D-1 Federal Laws and Regulations

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation | | | | |
|--|---|--|--|--|--|--|
| EPA Regulations | | | | | | |
| Toxic Substances Control Act (TSCA) – Section 6(b) | EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. | TCEP is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of TCEP as high-priority substance constitutes the initiation of the risk evaluation on the chemical. | | | | |
| Toxic Substances Control Act (TSCA) – Section 8(a) | The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. | TCEP manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011). | | | | |
| Toxic Substances Control Act (TSCA) – Section 8(b) | EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States. | TCEP was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995). The chemical is on the active inventory. | | | | |
| Toxic Substances Control Act (TSCA) – Section 4 | Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures. | Three chemical data submissions from test rules received for TCEP: all three were monitoring reports (1978, 1980, and 1981) (U.S. EPA, ChemView. Accessed April 3, 2019). | | | | |

D.2 State Laws and Regulations

Table_Apx D-2 State Laws and Regulations

| State Actions | Description of Action |
|---|--|
| State Prohibitions | Three states have adopted prohibitions for the use of TCEP in children's products, including Maryland (MD Health Gen § 24-306), New York (TRISfree Children and Babies Act (NY Envir Conser § 37-0701 <i>et seq.</i>)), Minnesota (Four flame Retardants in Furniture Foam and Children's Products (Minn. Stat. § 32SF.071)). |
| | California adopted a prohibition, effective on January 1, 2020, on the selling and distribution in commerce of new, not previously owned juvenile products, mattresses, or upholstered furniture that contains, or a constituent component of which contains, covered flame retardant chemicals at levels above 1,000 parts per million (A.B. 2998, Legislative Council, Sess. 2017-2018, C.A. 2018) |
| State Drinking Water Standards and Guidelines | Minnesota developed a health-based guidance value for TCEP in drinking water (Minn R. Chap. 4720) |
| Chemicals of High Concern to Children | Several states have adopted reporting laws for chemicals in children's products containing TCEP, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130). |
| Other | California listed TCEP on Proposition 65 in 1992 due to cancer (Cal Code Regs. Title 27, § 27001). |
| | California issued a Health Hazard Alert for TCEP (Hazard Evaluation System and Information Service, 2016). |
| | California lists TCEP as a designated priority chemical for biomonitoring (California SB 1379). |
| | TCEP is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). The regulation for Children's Foam-Padded Sleeping Products containing TCEP as a Priority Product went into effect on July 1, 2017: Manufacturers' of this product must notify the Department by September 1, 2017 (California Department of Toxic Substances Control. Accessed April 12, 2019.) |

D.3 International Laws and Regulations

 ${\bf Table_Apx~D\text{--}3~Regulatory~Actions~by~other~Governments,~Tribes,~and~International~Agreements}$

| Agreements Country/ Organization | Requirements and Restrictions |
|-----------------------------------|---|
| Canada | TCEP (Ethanol, 2-chloro-, phosphate (3:1)) is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). |
| | TCEP was added to Schedule 2 of the <i>Canada Consumer Product Safety Act (CCPSA)</i> , based on concerns for carcinogenicity and impaired fertility. (Government Canada Chemical Safety portal. Accessed April 10, 2019). |
| | In January 2013, a Significant New Activity was adopted for TCEP (<i>Canada Gazette</i> , April 3, 2014; Vol. 148, No. 9). |
| European Union | In June 2017, TCEP was added to Annex XIV of REACH (Authorisation List) with a sunset date of August 21, 2015 (European Chemicals Agency (ECHA, 2019) database. Accessed April 10, 2019). |
| | In 2010, TCEP was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 57C). |
| Australia | Ethanol, 2-chloro-, phosphate (3:1) (TCEP) was assessed under Human Health Tier II and III of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Uses reported include commercial: (NICNAS, 2016, <i>Ethanol, 2-chloro-, phosphate (3:1): Human health tier II assessment.</i> Accessed April 8, 2019) (NICNAS, 2017, <i>Ethanol, 2-chloro-, phosphate (3:1): Human health tier III assessment.</i> Accessed April 8, 2019). |
| Japan | TCEP is regulated in Japan under the following legislation: Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof Air Pollution Control Law (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. April 8, 2019). |
| Basel Convention | Waste substances and articles containing or contaminated with polychlorinated biphenyls (PCBs) and/or polychlorinated terphenyls (PCTs) and/or polybrominated biphenyls (PBBs) are listed as a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters. |

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for TCEP.

Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities.

E.1 Manufacture (Including Import)

E.1.1 Import

EPA expects that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and QC samples may be taken for analyses (EPA, 2018a).

E.2 Processing and Distribution

E.2.1 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. TCEP may undergo several processing steps and the processing is dependent on its downstream incorporation into articles, which is discussed in the next subsection (EPA, 2018b). Incorporated into an Article

E.2.2 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of TCEP-containing formulations or reaction products are dependent on the article (EPA, 2018b). For example, TCEP may be incorporated into aircraft interiors as a flame retardant (EPA-HQ-OPPT-2018-0476-0006). EPA plans to further investigate the use of TCEP being incorporated into articles during risk evaluation.

E.2.3 Recycling

EPA did not identify TCEP-specific information for recycling at this time; however, this chemical has been identified in articles that are commonly recycled such as insulation, plastics and foam. The processes for recycling these materials may include grinding, washing, and rinsing the recycled material and incorporating it into new formulations and articles as described more generally in Kirk Othmer (Borchardt, 2006). EPA has not identified specific worker activities related to the recycling TCEP-containing products. Based on EPA's knowledge, worker activities are anticipated to be exposed to TCEP from reclamation activities such as sorting, materials grinding steps and loading recovered materials into transport containers.

E.2.4 Uses Included in Scope

E.2.4.1 Aircraft Interiors and Aerospace Products

The Aerospace Industries Association (AIA, 2019) informed EPA that TCEP is used as a constituent

within products or formulations for the manufacture, operation and maintenance of aerospace products: it is used as an additive plasticizer and viscosity regulator with flame-retarding properties for polyurethane, polyesters, polyvinyl chloride and other polymers. TCEP is also used in the production of unsaturated polyester resins and in acrylic resins, adhesives and coatings. Specific aerospace industrial uses include resins and elastomeric coatings, polyurethane casting for aircraft interiors and as a flame retardant (AIA, 2019). Aceto Corporation, an importer of TCEP, has indicated to EPA that TCEP is used as a flame retardant for aircraft furniture (EPA-HO-OPPT-2018-0476-0015).

E.2.4.2 Building / Construction Materials

Aceto Corporation, an importer of TCEP, informed EPA that the building industry (roof insulation) is one potential field of application of the chemical (as used as a flame-retardant plasticizer in unsaturated polyester resins) (EPA-HQ-OPPT-2018-0476-0015). The European Commission (2012) stated that TCEP is used in the building industry, where roofing insulation accounted for more than 80% uses in the EU. Substances in Preparations in Nordic Countries (SPIN, 2019) reported TCEP for use in construction materials (up to 2003) and insulating materials (up to 2010). The World Health Organization's IARC Monographs on the Evaluation of Carcinogenic Risks to Humans identifies the use of TCEP as a flame retardant in rigid foams used for building insulation (WHO, 1999). NLM's PubChem states that TCEP is used in cast acrylic sheet and wood-resin composites such as particle board, citing a 2001 posting of Environment Canada's screening assessment report states that polymer products containing TCEP are used in the building industry, specifically roofing insulation (Environment Canada, 2009). TCEP has been identified in currently available foam products used in structural panels and insulation.

E.2.4.3 Foam Seating and Bedding Products

Aceto Corporation, an importer of TCEP, informed EPA that TCEP is sold into the furniture industry, and that the furniture industry uses TCEP as a flame-retardant plasticizer in unsaturated polyester resins (EPA-HQ-OPPT-2018-0476-0015). NLM's Hazardous Substance Databank (HSDB) identifies the use of TCEP with melamine in flexible urethane cushions and institutional mattresses (Kirk-Othmer Encyclopedia of Chemical Technology, as cited in HSDB, 2015). According to Substances in Preparations in Nordic Countries (SPIN, 2019) TCEP was reported for use in manufacture of furniture, until 2007.

E.2.4.4 Other: e.g., Laboratory Use

TCEP is used as a laboratory chemical, such as in a chemical standard mixture.

E.2.4.5 Paints and Coatings

For the 2012 CDR, Aceto Corporation reported the use of TCEP as a flame retardant for processing (incorporation into formulation, mixture, or reaction product) in the paint and coating manufacturing sector (U.S. EPA 2014). Aceto Corporation is the only current domestic manufacturer and they did not provide use information in the 2016 CDR. However, Aceto did inform EPA that coatings is one potential field of application of the chemical (EPA-HQ-OPPT-2018-0476-0015).

E.2.4.6 Fabric, Textile, and Leather Products

Aceto Corporation, an importer of TCEP, informed EPA that TCEP is sold into the textile industry, and that the textile industry uses TCEP as a flame-retardant plasticizer in unsaturated polyester resins (EPA-HQ-OPPT-2018-0476-0015). Rudolf-Venture Chemical Inc., an importer of TCEP as of 2015, is a supplier of chemicals specifically for the textile industry. The European Chemicals Agency (ECHA) registration dossier reports the use of TCEP in coatings at industrial and professional sites (ECHA, 2019). Environment Canada's screening assessment reports that TCEP is used in polymer products that are used in the textile industry, including back-coatings for carpets and upholstery (Environment

Canada, 2009). The European Commission also lists the textile industry (e.g., back-coatings for carpets and upholstery) as a use in the EU (EC, 2012).

E.2.4.7 Disposal

Disposal of a chemical should take into consideration the chemical's potential impact on air quality, migration to groundwater, effect on biological species, and disposal regulations (if any) (ATSDR, 2017). Currently, TCEP is not regulated under federal regulations as a hazardous waste. However, TCEP may be disposed of as a hazardous waste if it is present in or co-mingled with solvent mixtures that are RCRA regulated substances (EPA, 2018a).

Demolished building materials are classified as Construction and Demolition (C&D) waste, which may be disposed in municipal solid waste landfills (MSWLFs) or C&D landfills (EPA, 2018b; U.S. EPA, 2014) (HERO: 2533762).

E.3 Preliminary Occupational Exposure Data

EPA plans to consider reasonably available data and information related to worker exposure and environmental releases as they are identified during systematic review. Based on a preliminary data gathering, there are no OSHA Chemical Exposure and Health Data (CEHD) specific to TCEP.

Table_Apx E-1 Potentially Relevant Data Sources for Exposure Monitoring and Area Monitoring Data from NIOSH Health Hazard Evaluations for TCEP^a

| Year of Publication | Report Number | Facility Description | | | |
|---------------------|---|-------------------------------|--|--|--|
| 2019 | HHE-2016-0257-3333 | Electronics recycling company | | | |
| 2018 | HHE-2015-0050-3308 | Electronics recycling company | | | |
| 2017 | HHE-2014-0131-3268 | Gymnastics studios | | | |
| 1977 | HHE-77-39-400 Production of automobile upholstery | | | | |

^a Table includes HHEs identified to date

Appendix F SUPPORTING INFORMATION— CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES

Table_Apx F-1 Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

| Life Cycle Stage | Category | Subcategory | Release / Exposure Scenario | Exposure Pathway | Exposure Route | Receptor / Population | Plans to Evaluate | Rationale |
|---------------------|--|--|-----------------------------------|-----------------------------|---|--------------------------|---|--|
| | | | | Liquid Contact | Dermal | Workers | Yes | According to CDR, one submitter indicated that they import TCEP in liquid form. Exposure will occur if the imported material is repackaged |
| Manufacture | Import | | Workers | Yes | According to CDR, one submitter indicated that they imported TCEP in wet solid form. Exposure will occur if the imported material is repackaged | | | |
| | | | | | Workers, ONU | No | Mist generation is not expected during the import (i.e., repackaging) process. Because TCEP is imported as a liquid or wet solid, dust generation is not expected during the import (i.e., repackaging) process | |
| | | | | Liquid, Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| Processing | | Eleme netendent in | | Liquid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during unloading operations as TCEP is in liquid form. |
| | Incorporation into Formulation, Mixture, or Reaction product | into Formulation, Mixture, or Mixture, or Mixture, or Mixture, or | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during unloading operations as TCEP can be used/transported in wet solid form (according to one importer reporting to CDR). | |
| | | | | Mist, Dust | Inhalation | Workers, ONU | No | Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product). TCEP is in liquid form (or wet solid form according to one importer reporting to CDR), so dust generation is not expected during unloading operations. |

| Life Cycle Stage | Category | Subcategory | Release / Exposure Scenario | Exposure Pathway | Exposure Route | Receptor / Population | Plans to Evaluate | Rationale |
|---------------------|----------------------------|-----------------|-----------------------------------|-----------------------------|-------------------|--------------------------|----------------------|--|
| | | | | Liquid, Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | | | Liquid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during unloading operations, as TCEP is in liquid form. |
| | Incorporation into article | Flame retardant | Unloading | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during unloading operations, as TCEP can be used/transported in wet solid form (according to one importer reporting to CDR) |
| | | | | Mist, Dust | Inhalation | Workers, ONU | No | Mist generation is not expected during processing (incorporation into articles). TCEP is in liquid form (or wet solid form according to one importer reporting to CDR), so dust generation is not expected during unloading operations. |
| | | | | Liquid, Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | | | Liquid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during recycling, as TCEP can be incorporated in different liquid products |
| | Recycling | Recycling | | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during recycling, as TCEP can be incorporated in different solid products. |
| | Recycling | | Reclamation Activities | Mist | Inhalation | Workers, ONU | No | Mist generation is not expected during recycling |
| | | | | Dust | Inhalation | Workers, ONU | Yes | Dust exposure is expected during recycling, as particulates from solid products containing TCEP can be generated |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |

| Life Cycle Stage | Category | Subcategory | Release / Exposure Scenario | Exposure Pathway | Exposure Route | Receptor / Population | Plans to Evaluate | Rationale |
|----------------------------|------------------------|---|--|-------------------------|-------------------|--------------------------|----------------------|---|
| | | | | Liquid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during this use (Paints and Coatings), as paints and coatings containing TCEP are in liquid form. |
| | | | | Solid Contact | Dermal | Workers | No | Paints and coatings containing TCEP are not expected to be handled or used in solid form. |
| | Paints and Coatings | | Unloading; Spray Coating | Mist | Inhalation | Workers, ONU | Yes | The potential for exposure to TCEP suspended in mist exists during spray coating applications (Paints and Coatings) |
| | | | Applications | Dust | Inhalation | Workers, ONU | No | TCEP and paints containing TCEP are in liquid form so dust generation is not expected during this use (paints and coatings) |
| Industrial, Commercial, | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| Consumer Use | Other Use | Aircraft interiors and aerospace products | Use/Installati on of materials in | Liquid Contact | Dermal | Workers | No | TCEPPP and TCEPPP-containing article components are not expected to be handled or used in the liquid form. |
| | | | | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during the handling and manufacture of aircraft interiors and aerospace products containing article components with TCEP. |
| | | | aircraft interiors and aerospace products | Mist, Dust | Inhalation | Workers, ONU | No | Mist and dust generation is not expected during this use (aircraft interiors and aerospace products). |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | Laboratory chemicals | Use of laboratory chemicals | Liquid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during this use (laboratory chemicals), as TCEP is in liquid form. |

| Life Cycle Stage | Category | Subcategory | Release / Exposure Scenario | Exposure Pathway | Exposure Route | Receptor / Population | Plans to Evaluate | Rationale |
|---------------------|---|---|-----------------------------------|-------------------------|-------------------|--------------------------|----------------------|---|
| | | | | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during this use (laboratory chemicals), as TCEP can be used/transported in wet solid form (according to one importer reporting to CDR) |
| | | | | Mist, Dust | Inhalation | Workers, ONU | No | Mist generation is not expected during this use (laboratory chemicals). TCEP is in liquid form (or wet solid form according to one importer reporting to CDR), so dust generation is not expected during this use (laboratory chemicals). |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | Fabric, textile, and | Use of other textile products | Liquid Contact | Dermal | Workers | No | TCEPPP and TCEPPP-containing article components are not expected to be handled or used in the liquid form. |
| | Furnishing, | | | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during this use (fabric, textile, and leather products not covered elsewhere) during the handling of textiles and manufacture of products. |
| | Cleaning, Treatment Care Products | leather products not covered elsewhere | | Mist | Inhalation | Workers, ONU | No | Mist generation is not expected during this use (fabric, textile, and leather products not covered elsewhere). |
| | | | | Dust | Inhalation | Workers, ONU | Yes | Dust generation may occur as textiles are cut and incorporated into finished products. |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | Foam seating and bedding products | Unloading | Liquid Contact | Dermal | Workers | No | TCEPPP and TCEPPP-containing article components are not expected to be handled or used in the liquid form. |
| | | | | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during this use (foam seating and bedding products) during the handling of foam and manufacture of products. |

| Life Cycle Stage | Category | Subcategory | Release / Exposure Scenario | Exposure Pathway | Exposure Route | Receptor / Population | Plans to Evaluate | Rationale |
|---------------------|---------------------------------|--|--|-------------------------|-------------------|--------------------------|--|--|
| | | | | Mist | Inhalation | Workers, ONU | No | Mist generation is not expected during this use. |
| | | | | Dust | Inhalation | Workers, ONU | No | Dust generation is expected during this use (Foam Seating and Bedding Products), as TCEP-containing articles may need to be cut during finishing operations. |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | | Liquid Contact | Dermal | Workers | No | TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form. | |
| | | Building/constructi on materials not covered elsewhere Construction, int, Electrical, and Metal Products | Instillation/R euse/Demolit ion of materials in residential, public and commercial buildings, and other structures | Solid Contact | Dermal | Workers | Yes | The potential for exposure to workers from articles and article components containing TCEP exists during this use (building/construction materials not covered elsewhere). |
| | | | | Mist | Inhalation | Workers, ONU | No | Mist generation is not expected during this use (building/construction materials not covered elsewhere). |
| | Paint, Electrical, and Metal | | | Dust | Inhalation | Worker, ONU | Yes | Dust generation is expected during this use (building/construction materials not covered elsewhere). |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | Wood and engineered wood products | Use of wood and engineering wood products | Liquid Contact | Dermal | Workers | No | TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form |
| | | | | Solid Contact | Dermal | Workers | Yes | The potential for exposures to workers exists during this use (wood and engineering wood products) during the handling and manufacture of wood and engineered wood products. |

| Life Cycle Stage | Category | Subcategory | Release / Exposure Scenario | Exposure Pathway | Exposure Route | Receptor / Population | Plans to Evaluate | Rationale |
|---------------------|---------------------------|------------------------------------|-----------------------------------|-------------------------|-------------------|--------------------------|----------------------|---|
| | | | | Mist, Dust | Inhalation | Workers, ONU | No | Mist generation is not expected during this use (wood and engineering wood products). Dust generation is not expected during this use (wood and engineering wood products). |
| | | | | Liquid/Solid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | Disposal of TCEP containing wastes | Worker handling of wastes | Liquid Contact | Dermal | Worker | Yes | Dermal exposure is expected for this condition of use |
| | Waste Handling. | | | Dust | Inhalation | Worker | Yes | TCEP may be present in solid material. EPA plans to evaluate the inhalation pathway. |
| Disposal Ti | Treatment and Disposal | | | Liquid Contact | Dermal | ONU | No | Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical. |
| | | | | Dust | Inhalation | ONU | Yes | TCEP may be present in solid material. EPA plans to evaluate the inhalation pathway |

Appendix G SUPPORTING INFORMATION—CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USE

Table_Apx G-1 Consumer Exposure Conceptual Model Supporting Table

| Life Cycle Stage | Category | Subcategory | Release from source | Exposure Pathway | Route | Receptor | Plans to Evaluate | Rationale |
|---------------------|---|--|--|----------------------------|------------|--------------------------|----------------------|---|
| | | | Direct contact via application of paints and coatings containing TCEP | Liquid Contact | Dermal | Consumers | Yes | The potential for exposures exists during this use (Paints and Coatings), as paints and coatings containing TCEP are in liquid form. |
| Consumer Use | Paints and Coatings | Paints and Coatings | | Vapor | Inhalation | Consumers/ Bystanders | Yes | Due to the volatility of TCEP (VP = 0.06 mmHg) at room temperature, inhalation exposure to TCEP in the vapor phase is possible. |
| | | | | Mist | Inhalation | Consumers/ Bystanders | Yes | The potential for exposure to TCEP suspended in mist exists during spray coating applications (Paints and Coatings) |
| | Construction, | Wood and engineered wood products | Direct contact through use of electrical and electronic products made containing TCEP | Air/Particulate | Inhalation | Consumers/ Bystanders | Yes | Inhalation of air and/or particles from electrical and electronic products containing TCEP may occur for this condition of use. EPA plans to analyze inhalation exposure. |
| | | | | Dust | Ingestion | Consumers/ Bystanders | Yes | Ingestion of dust from electrical and electronic products containing TCEP may occur for this condition of use. EPA plans to analyze dust exposure via ingestion. |
| Consumer Use | Paint, Electrical, and Metal Products | | | Article/Product Contact | Dermal | Consumers | Yes | Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure. |
| | | Building/ construction materials not covered elsewhere | Direct contact through use of building/ construction materials made containing TCEP | Air/Particulate | Inhalation | Consumers/ Bystanders | Yes | Inhalation of air and/or particles from building/construction materials containing TCEP may occur for this condition of use. EPA plans to analyze inhalation exposure. |
| | | | | Dust | Ingestion | Consumers/ Bystanders | Yes | Ingestion of dust from building/construction materials containing TCEP may occur for this |

| Life Cycle Stage | Category | Subcategory | Release from source | Exposure Pathway | Route | Receptor | Plans to Evaluate | Rationale |
|-----------------------|--|---|--|-----------------------------|------------|--------------------------|----------------------|--|
| | | | | | | | | condition of use. EPA plans to analyze dust exposure via ingestion. |
| | | | | Article/Product Contact | Dermal | Consumers | Yes | Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure. |
| Consumer Use Cleaning | | | Direct contact through use of products/articles containing TCEP | Air/Particulate | Inhalation | Consumers/ Bystanders | Yes | Inhalation via air and/or particulate exposure may occur during product/article use. EPA plans to analyze inhalation exposure. |
| | Furnishing, Cleaning, Treatment/ | Fabric, textile, and leather products not covered elsewhere | | Dust | Ingestion | Consumers/ Bystanders | Yes | Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion. |
| | Care Products | | | Article/Product Contact | Dermal | Consumers | Yes | Dermal exposure may occur via use of articles containing TCEP. EPA plans to analyze dermal exposure. |
| | | | | Article/Product Mouthing | Ingestion | Bystanders | Yes | Ingestion via object to mouth or subsequent hand to mouth from product dermal contact. EPA plans to analyze mouthing via ingestion. |
| | | | Direct contact through use of products/articles containing TCEP | Air/Particulate | Inhalation | Consumers/ Bystanders | Yes | Inhalation via air and/or particulate exposure may occur during product/article use. EPA plans to analyze inhalation exposure. |
| Consumer Use | Furnishing, Cleaning, | Foam setting and | | Dust | Ingestion | Consumers/ Bystanders | Yes | Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion. |
| | Treatment/ Care Products | bedding products | | Article/Product Contact | Dermal | Consumers | Yes | Dermal exposure may occur via use of articles containing TCEP. EPA plans to analyze dermal exposure. |
| | | | | Article/Product Mouthing | Ingestion | Bystanders | Yes | Ingestion via object to mouth or subsequent hand to mouth from product dermal contact. EPA plans to analyze mouthing via ingestion. |

| Life Cycle Stage | Category | Subcategory | Release from source | Exposure Pathway | Route | Receptor | Plans to Evaluate | Rationale |
|---------------------|---|--|---|----------------------------|------------|--------------------------------|----------------------|--|
| | | Wastewater, Liquid wastes and solid wastes | Direct contact through use of products/articles containing TCEP | Article/Product Contact | Dermal | Consumers | Yes | Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure. |
| | | | | Dust | Ingestion | Consumers | Yes | Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion. |
| | Wastewater, Liquid wastes and solid wastes | | | Air/Particulate | Inhalation | Consumers and Bystanders | Yes | Inhalation of air and/or particles from articles/products containing TCEP may occur for this condition of use. EPA plans to analyze inhalation exposure. |
| | | | Long-term emission/mass- transfer through use of products containing TCEP | Dust | Ingestion | Consumers | Yes | Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion. |
| | | | | Air/Particulate | Inhalation | Consumers and Bystanders | Yes | Inhalation of air and/or particles from articles/products containing TCEP may occur for this condition of use, EPA plans to analyze inhalation exposure |

Appendix H SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR ENVIRONMENTAL RELEASES AND WASTES

<u>Table_Apx H-1 General Population and Environmental Exposure Conceptual Model Supporting Table</u>

| Life Cycle Stage | Category | Release | Exposure Pathway / Media | Exposure Routes | Receptor / Population | Plans to Evaluate | Rationale |
|------------------------|--------------------------------|--|--|---|---|----------------------|--|
| | | | Near facility ambient air concentrations | Inhalation | General Population | Yes | TCEP deposition to nearby bodies of water and soil are |
| | Emissions to Air | Emissions to Air | Indirect deposition to | Oral Dermal | General Population | Yes | expected exposure pathways, not covered under other EPA |
| | | | nearby bodies of water and soil catchments | TBD | Aquatic and Terrestrial Receptors | Yes | regulations, and, therefore in scope. |
| | | Industrial pre- treatment and wastewater treatment, or POTW | Direct release into surface water and | TBD | Aquatic and Terrestrial Receptors | Yes | EPA plans to analyze the release of TCEP into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors. |
| All | | | indirect partitioning to sediment | Oral Dermal | General Population | Yes | EPA plans to analyze the release of TCEP into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population. |
| | Wastewater or Liquid Wastes | | Drinking Water via Surface or Ground Water | Oral Dermal and Inhalation (e.g. showering) | General Population | Yes | EPA plans to analyze the release of TCEP into surface water and indirect partitioning to drinking water. |
| | | | Biosolids: application to soil and/or migration to groundwater | Oral (e.g. ingestion of soil) Inhalation | General Population | Yes | EPA plans to analyze the pathway from biosolids to the general population and terrestrial |
| | | | and/or surface water | TBD | Terrestrial receptors | Yes | species. |

| Life Cycle Stage | Category | Release | Exposure Pathway / Media | Exposure Routes | Receptor / Population | Plans to Evaluate | Rationale |
|------------------------|----------------------------|--|--|--------------------|---|----------------------|---|
| | Colid and Liquid | Municipal landfill | Leachate to soil, ground | Oral Dermal | General Population | Yes | EPA plans to analyze the |
| Disposal | Solid and Liquid Wastes | Municipal landfill and other land disposal | water and/or mitigation to surface water | TBD | Aquatic and Terrestrial Receptors | res | pathway from municipal landfills and other land disposal to the general population, aquatic and terrestrial receptors. |